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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,474	04/07/2004	Preeti Lal	039386-1568	7560

22428 7590 02/01/2007
FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
LANDSMAN, ROBERT S	
ART UNIT	PAPER NUMBER
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

TH

Office Action Summary	Application No.	Applicant(s)	
	10/820,474	LAL ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence Comparisons A and B*.

DETAILED ACTION

1. Formal Matters

A. The Election mailed 1/5/07 has been entered into the record.

B. Applicants elected Group II. Since no traversal has been provided the Election is being treated as one without traverse. However, Applicants canceled all previously pending claims (1-55) and added new claims 56-64, all drawn to Group II.

2. Specification

A. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Polynucleotides encoding signal peptide-containing molecules.

B. The specification is objected to since no Tables can be found in the specification.

C. The first line of spec does not claim priority to 09/720,533, as recited on the Bibliographic Data Sheet.

3. Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

A. Claims 56-64 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, substantial and credible asserted utility or a well established utility. These claims are directed to a polynucleotide encoding HSPPs which are at least 95% identical to SEQ ID NO:43, or which comprise SEQ ID NO:177. However, the invention encompassed by these claims has no apparent or disclosed patentable utility. This rejection is consistent with the current utility guidelines, published 1/5/01, 66 FR 1092. The instant application has provided a description of an isolated protein. However, the instant application does not disclose a specific and substantial biological role of this protein or its significance.

However, it is clear from the instant specification that the claimed receptor is what is termed an "orphan receptor" in the art. The instant application does not disclose the biological role of the claimed protein or its significance. Applicants disclose in the specification that the claimed receptor is believed to be a signal peptide-containing protein. However, the basis that the receptor of the present invention is a HSPP is not predictive of a use. There is little doubt that, after complete characterization, this protein will probably be found to have a patentable utility. This further characterization, however, is part of the act of invention and, until it has been undertaken, Applicants' claimed invention is incomplete.

The instant claims are drawn to a polynucleotide encoding a protein which has a yet undetermined function or biological significance. There is no actual and specific significance which can be attributed to said protein identified in the specification. For this reason, the instant invention is incomplete. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which bind to and/or mediate activity of the said receptor is clearly to use it as the object of further research which has been determined by the courts to be a non-patentable utility. Since the instant specification does not disclose a "real-world" use for said protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful.

Furthermore, since the nucleic acids of the invention are not supported by a specific and substantial asserted utility or a well established utility, the vector, host cell, polypeptide and method for producing the claimed polypeptide also lack utility.

4. Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 56-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to use the instant invention. Specifically, since the claimed invention is not supported by a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

B. Furthermore, even if claims 56-64 possessed utility under 35 USC 101, they would still be rejected under 35 U.S.C. 112, first paragraph, because the specification, while then being enabling for SEQ ID NO:43 and 177, does not reasonably provide enablement for polynucleotides encoding proteins which are at least 95% identical to SEQ ID NO:43 or 177. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to claiming all nucleic acid molecules which are "**at least 95%**" identical to SEQ ID NO:177 or which encode SEQ ID NO:43. Nucleic acid molecules which are "at least 95% identical" to SEQ ID NO:177 would have one or more nucleic acid substitutions to SEQ ID NO:177. Similarly, proteins which are "at least 95%" identical to the proteins of SEQ ID NO:43 would have one or more amino acid substitutions, deletions, insertions and/or additions to the protein encoded for by SEQ ID NO:43.

Applicants provide no guidance or working examples of nucleic acid molecules which are at least 95% identical to SEQ ID NO:177, or which are "at least 95%" identical to SEQ ID NO:43, nor do they provide a *function* of these nucleic acid molecules, or of the proteins which they encode. Furthermore, it is not predictable to one of ordinary skill in the art what the functions of these nucleic acids, or the proteins which they encode, are.

In summary, the breadth of the claims is extensive with regard to Applicants claiming all nucleic acids either 95% identical to SEQ ID NO:177, or which encode SEQ ID NO:43. There is also a lack of guidance and working examples of these nucleic acid molecules and proteins. Applicants do not provide a function of these nucleic acid molecules, or a function of the proteins which they encode. These factors, along with the lack of predictability to one of ordinary skill in the art as to what the functions of these nucleic acids are, or the proteins which they encode are leads the Examiner to hold that undue experimentation is necessary to practice the invention as claimed.

5. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 56-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. Nucleic acid molecules which are "at least 95% identical" to SEQ ID NO:177 would have one or more nucleic acid substitutions to SEQ ID NO:177. Similarly, proteins which are "at least 95%" identical to the proteins of SEQ ID NO:43 would have one or more amino acid substitutions, deletions, insertions and/or additions to the protein encoded for by SEQ ID NO:43.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the nucleic acid or protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO:43 and 177 alone are insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

6. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 56, 59-60 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by Gurney et al. (US20040018980A1). The claims recite an isolated polynucleotide at least 95% identical to SEQ ID NO:177 or which encodes a protein at least 95% identical to SEQ ID NO:43. The polynucleotide of Gurney is 99.8% identical to SEQ ID NO:177 (Sequence Comparison A). therefore, since there is only

one base different between the sequences, it would be expected that the polynucleotide of Gurney would inherently encode a protein at least 95% identical to SEQ ID NO:43. The claims also recite the polynucleotide linked to a promoter, an isolated host cell, and a method of making protein. Gurney meet these limitations ([0119]-[0121]).

7. Art of Interest

A. No rejection under 35 USC 102 is being made over NCI-CGAP (Accession No. AA524300) since no prima facie case could be made by the examiner that the polypeptide of NCI has any more utility than that disclosed by the present invention due to the fact that the protein of NCI is an EST.

8. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM – 7 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman
Primary Examiner
Art Unit 1647

Sequence Comparism A

; Sequence 17, Application US/10461060
; Publication No. US20040018980A1
; GENERAL INFORMATION:
; APPLICANT: Gurney, Austin L.
; APPLICANT: Hebert, Caroline
; APPLICANT: Henzel, William J.
; APPLICANT: Kabakoff, Rhona
; APPLICANT: Shelton, David L.
; APPLICANT: Tumas, Daniel B.
; TITLE OF INVENTION: NOVEL FIZZ PROTEINS
; FILE REFERENCE: P1366R3
; CURRENT APPLICATION NUMBER: US/10/461,060
; CURRENT FILING DATE: 2003-09-18
; PRIOR APPLICATION NUMBER: US/09/380,913
; PRIOR FILING DATE: 1999-09-09
; PRIOR APPLICATION NUMBER: US 60/082,999
; PRIOR FILING DATE: 1998-04-24
; PRIOR APPLICATION NUMBER: US 60/085,149
; PRIOR FILING DATE: 1998-05-12
; PRIOR APPLICATION NUMBER: US 60/100,263
; PRIOR FILING DATE: 1998-09-14
; NUMBER OF SEQ ID NOS: 33
; SEQ ID NO 17
; LENGTH: 703
; TYPE: DNA
; ORGANISM: Homo sapien
US-10-461-060-17

Query Match 99.8%; Score 680.4; DB 8; Length 703;
Best Local Similarity 99.9%; Pred. No. 9.3e-223;
Matches 681; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

```
Qy          1 TCTGAATGTTTTGGTGAATAAATCTGTTCTTCAGCAACCCTACCTGCTTCTCCAAACTGC 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 TCTGAATGTTTTGGTGAATAAATCTGTTCTTCAGCAACCCTACCTGCTTCTCCAAACTGC 60

Qy         61 CTAAAGAGATCCAGTACTGATGACGCTGTTCTTCCATCTTTACTCCCTGGAAACTAACCA 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 CTAAAGAGATCCAGTACTGATGACGCTGTTCTTCCATCTTTACTCCCTGGAAACTAACCA 120

Qy        121 CGTTGTCTTCTTTCCTTCACCACCACCCAGGAGCTCAGAGATCTAAGCTGCTTTCCATCT 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 CGTTGTCTTCTTTCCTTCACCACCACCCAGGAGCTCAGAGATCTAAGCTGCTTTCCATCT 180

Qy        181 TTTCTCCCAGCCCCAGGACACTGACTCTGTACAGGATGGGGCCGTCCTCTTGCCTCCTTC 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 TTTCTCCCAGCCCCAGGACACTGACTCTGTACAGGATGGGGCCGTCCTCTTGCCTCCTTC 240

Qy        241 TCATCCTAATCCCCCTTCTCCAGCTGATCAACCTGGGGAGTACTCAGTGTTCCTTAGACT 300
              |||||||||||||||||||||||||||||| ||||||||||||||||||||||||||||
Db        241 TCATCCTAATCCCCCTTCTCCAGCTGATCAACCCGGGGAGTACTCAGTGTTCCTTAGACT 300

Qy        301 CCGTTATGGATAAGAAGATCAAGGATGTTCTCAACAGTCTAGAGTACAGTCCCTCTCCTA 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 CCGTTATGGATAAGAAGATCAAGGATGTTCTCAACAGTCTAGAGTACAGTCCCTCTCCTA 360

Qy        361 TAAGCAAGAAGCTCTCGTGTGCTAGTGTCAAAAGCCAAGGCAGACCGTCCTCCTGCCCTG 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 TAAGCAAGAAGCTCTCGTGTGCTAGTGTCAAAAGCCAAGGCAGACCGTCCTCCTGCCCTG 420

Qy        421 CTGGGATGGCTGTCACTGGCTGTGCTTGTGGCTATGGCTGTGGTTCGTGGGATGTTCAGC 480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        421 CTGGGATGGCTGTCACTGGCTGTGCTTGTGGCTATGGCTGTGGTTCGTGGGATGTTCAGC 480
```

B

samples and primed with a Not I - oligo(dT) primer. Double-stranded cDNA was ligated to Eco RI adaptors (Pharmacia), digested with Not I and cloned into the Not I and Eco RI sites of the modified pT7T3 vector. Library went through one round of normalization. "

ORIGIN

Alignment Scores:

Pred. No.:	1.26e-47	Length:	577
Score:	585.00	Matches:	110
Percent Similarity:	98.2%	Conservative:	0
Best Local Similarity:	98.2%	Mismatches:	1
Query Match:	96.7%	Indels:	1
DB:	1	Gaps:	0

US-10-820-474A-43 (1-111) x AA524300 (1-577)

```
Qy          1 MetGlyProSerSerCysLeuLeuLeuIleLeuIleProLeuLeuGlnLeuIleAsnLeu 20
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        477 ATGGGGCCGTCCTCTTGCCTCCTTCTCATCCTAATCCCCCTTCTCCAGCTGATCAACCCG 418

Qy         21 GlySerThrGlnCysSerLeuAspSerValMetAspLysLysIleLysAspValLeuAsn 40
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        417 GGGAGTACTCAGTGTTCCTTAGACTCCGTTATGGATAAGAAGATCAAGGATGTTCTCAAC 358

Qy         41 SerLeuGluTyrSerProSerProIleSerLysLysLeuSerCysAlaSerValLysSer 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        357 AGTCTAGAGTACAGTCCCTCTCCTATAAGCAAGAAGCTCTCGTGTGCTAGTGTCAAAAGC 298

Qy         61 GlnGlyArgProSerSer-CysProAlaGlyMetAlaValThrGlyCysAlaCysGlyTy 80
              |||||||||||||||||| ||||||||||||||||||||||||||||||||||||||||
Db        297 CAAGGCAGACCGTCCTCACTGCCCTGCTGGGATGGCTGTCACTGGCTGTGCTTGTGGCTA 238

Qy         80 rGlyCysGlySerTrpAspValGlnLeuGluThrThrCysHisCysGlnCysSerValVa 100
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        237 TGGCTGTGGTTCGTGGGATGTTCAGCTGGAAACCACCTGCCACTGCCAGTGCAGTGTGGT 178

Qy        100 lAspTrpThrThrAlaArgCysCysHisLeuThr 111
              |||||||||||||||||||||||||||||||||
Db        177 GGACTGGACCACTGCCCGCTGCTGCCACCTGACC 144
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Qy        481 TGGAAACCACCTGCCACTGCCAGTGCAGTGTGGTGGACTGGACCACTGCCCGCTGCTGCC 540
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        481 TGGAAACCACCTGCCACTGCCAGTGCAGTGTGGTGGACTGGACCACTGCCCGCTGCTGCC 540

Qy        541 ACCTGACCTGACAGGGAGGAGGCTGAGAACTCAGTTTTGTGACCATGACAGTAATGAAAC 600
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        541 ACCTGACCTGACAGGGAGGAGGCTGAGAACTCAGTTTTGTGACCATGACAGTAATGAAAC 600

Qy        601 CAGGGTCCCAACCAAGAAATCTAACTCAAACGTCCCACTTCATTTGTTCCATTCCTGATT 660
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        601 CAGGGTCCCAACCAAGAAATCTAACTCAAACGTCCCACTTCATTTGTTCCATTCCTGATT 660

Qy        661 CTTGGGTAATAAAGACAAACTT 682
              |||||||||||||||||||||||
Db        661 CTTGGGTAATAAAGACAAACTT 682
```

Sequence Comparism B

```
LOCUS       AA524300                577 bp    mRNA    linear   EST 21-AUG-1997
DEFINITION  ng32g12.s1 NCI_CGAP_Co3 Homo sapiens cDNA clone IMAGE:936550 3',
            mRNA sequence.
ACCESSION   AA524300
VERSION     AA524300.1  GI:2265228
KEYWORDS    EST.
SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Euarchontoglires; Primates; Catarrhini;
            Hominidae; Homo.
REFERENCE   1  (bases 1 to 577)
  AUTHORS   NCI-CGAP http://www.ncbi.nlm.nih.gov/ncicgap.
  TITLE     National Cancer Institute, Cancer Genome Anatomy Project (CGAP),
            Tumor Gene Index
  JOURNAL   Unpublished (1997)
COMMENT     Contact: Robert Strausberg, Ph.D.
            Email: cgapbs-r@mail.nih.gov
            Tissue Procurement: Elias Campo, M.D., Michael R. Emmert-Buck,
            M.D., Ph.D.
             cDNA Library Preparation: M. Bento Soares, Ph.D.
             cDNA Library Arraying: Greg Lennon, Ph.D.
             DNA Sequencing by: Washington University Genome Sequencing Center
             Clone distribution: NCI-CGAP clone distribution information can be
            found through the I.M.A.G.E. Consortium/LLNL at:
            www-bio.llnl.gov/bbrp/image/image.html
            Insert Length: 919   Std Error: 0.00
            Seq primer: -40m13 fwd. ET from Amersham
            High quality sequence stop: 252.
FEATURES             Location/Qualifiers
     source          1. .577
                     /organism="Homo sapiens"
                     /mol_type="mRNA"
                     /db_xref="taxon:9606"
                     /clone="IMAGE:936550"
                     /sex="pooled"
                     /tissue_type="colon"
                     /lab_host="DH10B"
                     /clone_lib="NCI_CGAP_Co3"
                     /note="Vector: pT7T3D-PacI; Site_1: Not I; Site_2: Eco RI;
                     1st strand cDNA was prepared from 12 pooled bulk tumor
```